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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,694	06/15/2001	Jon Duvick	35718/208255 (5718-111C)	1574

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EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	19

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/882,694	DUVICK et al
Examiner	**Art Unit**
Medina Ibrahim	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *May 8, 2003* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see NOTE below);

(c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *the method comprising three steps of stably integrating into the genome of a plant cell three different nucleotide sequences at once and transgenic plant cell, plant and seed comprising said nucleotide sequences*

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
arguments re written desription rejection are duplicates of what have been previously addressed

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: *2, 11, 30, and 32*

Claim(s) rejected: *1, 3-10, 12-29, 31, and 33*

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). *12*.

10. ☒ Other: *The amendment of 4/11/03 will be entered. see attached for explanation. The supplemental amendment of 5/08/03 is not entered for the reasons discussed*

Applicant's response filed 4/11/03 in reply to the Final Office action of 2/11/02 has been entered. Initialed and signed copy of the IDS form 1449 filed 06/15/01 which was inadvertently left from the last Office actions is attached to the instant Office action.

Claims 30 and 32 are newly amended.

Written Description

Claims 1, 3-10, 12-29, 31 and 33 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the same reasons of record as set forth in the last Office actions. Applicants' arguments filed 4/11/03 have been fully considered but are not all persuasive.

Applicant's arguments regarding the 112, 1st rejections to claims encompassing nucleotide sequences having at least 95% sequence identity to the exemplified sequences are found persuasive. However, the arguments that claims drawn to a method that employs a nucleotide sequence encoding a polypeptide having fumonisin esterase or amine oxidase activity, and plant/plant cells stably transformed with said nucleotide sequence meet the written description requirement are not deemed persuasive for the following reasons: the claims encompassing any and all nucleotide

sequences encoding a polypeptides having fumonisin esterase or amine oxidase activity are described only by function. There is known correlation between function and structure of a polypeptide having fumonisin esterase or amine oxidase activity. The exemplary, primary nucleotide sequences described in the specification are from a single organism *Exophiala spinifera*, and are not a representative number of species of the claimed genus. No common structural features or any other identifying characteristics are disclosed for the claimed genus, which would allow one skilled in the art to visualize what will be the structure of the non-described sequences. While the claimed nucleotide sequences are all required to encode a polypeptide having fumonisin esterase or amine oxidase activity, this common feature is a functional feature rather than structural. These written description requirements are properly based on case laws of *Regents of the university of California v. Eli Lilly & Co*; cited in the previous Office actions and *Ex Parte Maizel*, citing *Amgen Inc*; cited by Applicants in the response and . Therefore, in view of the above, one skilled in the art would not recognize from the disclosure that Applicant was in possession of the claimed method that employs any and all nucleotide sequences encoding a polypeptide having fumonisin esterase or amine oxidase activity and plant/plant cell/seed stably transformed with said nucleotide sequence, at the time this application was filed.

Applicant's arguments that claims 31 and 33 encompassing 90% sequence identity to exemplified sequences are adequately described are not deemed persuasive

for the following reasons: firstly, while 90% sequence identity is a predictable structure, the functional activity of the nucleotide sequence cannot be predicted based on sequence identity. Applicant has not described a nucleotide sequence having ta least 90% sequenc identity and still encoding a polypeptide having the desired fumonisin detoxification activity. Secondly, unlike Example 14 of the Revised Interim Written Descrition Guidelines, the sequence identity is based on a nucleotide sequence and is less than 95%.

In addition, Applicant's arguments that one skilled in the art using the guidance of the specification would be able to identify, isolate, and use a primary nucleotide sequence having the limitations of the claims are related to enablement issues rather than written description.

Claims 2, 11, 30, and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800